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|-------------------------------|------------------------|---------------------|--|
| Notice of Allowability | Application No. | Applicant(s) | |
| | 09/471,703 | MERENKOVA, IRENA N. | |
| | Examiner | Art Unit | |
| | Jehanne E Souaya | 1634 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to June 2, 2003.
2. ☒ The allowed claim(s) is/are 69 and 71-88.
3. ☒ The drawings filed on 23 December 1999 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.
5. ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 - (a) ☐ The translation of the foreign language provisional application has been received.
6. ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. **THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

7. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
8. ☐ CORRECTED DRAWINGS must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No. _____.
 - (b) ☐ including changes required by the proposed drawing correction filed _____, which has been approved by the Examiner.
 - (c) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No. _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet.

9. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--|---|
| 1 <input type="checkbox"/> Notice of References Cited (PTO-892) | 2 <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3 <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 4 <input checked="" type="checkbox"/> Interview Summary (PTO-413), Paper No. _____. |
| 5 <input type="checkbox"/> Information Disclosure Statements (PTO-1449), Paper No. _____. | 6 <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 7 <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material | 8 <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9 <input type="checkbox"/> Other _____. |

EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Carl Bozicevic on October 2, 2003.

The application has been amended as follows:

In claim 71, line 3, insert the word --site-- after the word 'polymorphic'.

In claim 76, line 1, delete the recitation of "reaction" and insert instead --primer extension--.

REASONS FOR ALLOWANCE

2. The following is an examiner's statement of reasons for allowance: The claims are drawn to methods involving: detecting the identity of a polymorphic nucleotide in a target sequence (or a plurality of target sequences) having at least two known variant nucleotides at a polymorphic site comprising 1) performing a primer extension reaction with the target sequence using an extension reaction mixture comprising a primer that specifically hybridizes to the target sequence such that there is at least a one or more nucleotide gap between the 3' terminus of the primer and the polymorphic site on the target sequence, a mixture of dNTPs or rNTPs providing for at least one nucleotide extension of the primer and wherein the mixture excludes a dNTP or rNTP complementary to one of said variant nucleotides at the polymorphic site and further wherein the dNTPs or rNTPs are not detectably labeled, and wherein extension is performed in the absence of ddNTP, 2) analyzing primer extension products, and 3) wherein the length of the primer

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extension products is indicative of the identity of the variant nucleotides at the polymorphic site. The closest prior art is that of Soderlund in view of Hoogendorn and Kuppaswamy as set for in sections 6-8 of the previous office action mailed 5/27/2003. The claims are allowable over the closest prior art because Soderlund in view of Hoogendorn and Kuppaswamy (and further in view of Gibson or Krook) do not teach or fairly suggest 1) a primer extension method wherein the primer that specifically hybridizes to the target sequence does so with a one or more nucleotide gap between the 3' terminus of the primer and the polymorphic site on the target sequence *and* 2) in the absence of ddNTP *and* 3) a mixture of unlabeled, unmodified dNTPs or rNTPs lacking a dNTP or rNTP complementary to one of the variants at the polymorphic site, such that the length of the primer extension products is indicative of the identity of the variant nucleotides at the polymorphic site. These limitations in the claims allow for a single reaction to be used to determine not only the identity of the variants but also whether the target is homozygous or heterozygous at the polymorphic site. Two reactions are required in the cited references to determine homozygosity or heterozygosity. Therefore, the claims are allowable over the cited reference because none of the cited references alone or in combination teach or suggest such limitations.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

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3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jehanne Souaya whose telephone number is (703) 308-6565. The examiner can normally be reached Monday-Friday from 9:00 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax phone number for this Group is (703) 872-9306.

Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Jehanne Souaya
Primary Examiner
Art Unit 1634

• 10/2/03